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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,789	09/12/2001	Charlie Ricci	018413-378	8809

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,789	RICCI ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 20-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16, 20-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are:. a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on January 20, 2004 ("Amendment") has been entered. Claims 16, 20-32 are pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory US Patent 5,951,599 in view of Chuter et al (J Vasc Surg 2000; 31:122-33), May (J Vasc Surg 2000; 32:124-129) and Evans et al US Patent 5,695,480.[1]

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Accordingly, the rejection is maintained for the reasons of record.

Applicants first argue that the kit of McCrory does not teach stent-grafts and is not concerned with endoleak nor with endoleak repair.[2] In reply Examiner states that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the combined teachings of references meet the structural elements of the instant kits,

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[1] Examiner noted Applicant's preservation of the right to remove Chuter and May references based on showing an effective priority date that would remove these references based on after filing publication date. See *Applicant's Amendment* at fn. 2. However, Examiner points out that the contrary to Applicant's assessment, the effective priority

therefore, the combined teachings of the references meets the limitations of the instant claims.

More specifically, the intent of McCrory to treat or repair endoleak is immaterial to the motivation of one of ordinary skill in the art to combine McCrory with the cited references to form a surgical kit. The reasoning employed by the Examiner relies on the question that whether one of ordinary skill in the art would have been motivated to use McCrory's stent-graft in a surgical kit that essentially comprise the same elements as those instantly claimed, regardless of the intended use.

Nevertheless, Examiner points out that contrary to Applicant's arguments the motivation does not rely on a desire to improve the function of McCrory's stent or function thereof. Rather, Examiner assessed the inquiry that would it be reasonable for a skilled artisan to assemble a kit for ease of access during a surgical process? It is Examiner's position that for at least convenience and ease of access, one of ordinary skill in the art would have been motivated to combine the teachings of the cited references to practice a surgical goal similar to McCrory's.

McCrory at numerous places asserts the use of a polymeric embolic composition capable of forming a mass at an abdominal aortic aneurysm.[3] Clearly, the microcatheter used by McCrory is suitable for delivering a polymeric embolic composition. Contrary to Applicant's assertion, McCrory is not distinguishable from the instant claims, because its

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date of the instant application is March 20, 2000, not March 1999, because March 2000 is the earliest time the Applicants appear to have envisioned the use of stent-graft in their kits.

[2] See page 10, 2nd full paragraph of the Amendment.

[3] See for example, col 4, line 3-5; col 5, lines 30-35 and col 6, lines 45-59.

attempts to minimize the flow of blood into the aneurismal sac[4] and such attempt reads on the element (d) of the instant claim 16. Namely, element (d) is directed to a stent-graft capable of inhibiting but not completely arresting blood flow into the abdominal aortic aneurysm. There is no evidence provided that McCrory's attempt is not capable of performing such function, because for at least the reasons set forth in May McCrory's stent are substantially similar in function as those instantly claimed.

Applicant then turns to Chutter and alleges that nowhere in Chutter describes "stent-grafts" for treating abdominal aortic aneurysms. In response, Examiner states that Chutter's procedure employed such stent-grafts that are used for abdominal aortic aneurysm ("AAA"). [5] In fact, the eligibility criteria for patient's undergoing his procedure were to have already undergone a treatment for AAA.[6] Further, in numerous places Chutter refers to the use of custom-made aortomonoiliac stent grafts.[7] Therefore, Chutter's stent-graft is used for treating AAA. May was also used to show that both stent and stent-grafts are shown to be equally effective in treating abdominal aortic aneurysm. [8] Therefore, selecting one over the other appears to be a matter of surgeon's choice.

Further, contrary to Applicants arguments that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

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[4] See Amendment at page 10, 2nd and 3rd paragraph.
[5] See Chutter's Abstract. Also seepages 123-125.
[6] See Chutter's Table I.
[7] See for example the abstract under the heading *Results*.

within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, all elements of the instant claims are taught in the art and the references are combinable for the reasons of record and described above.

Examiner also points out that one of the factual inquiries required to be considered for the purposes of an obviousness rejection is the level of ordinary skill in the art. Here, Examiner has repeatedly pointed out during the prosecution that assembling a surgical kit for ease of convenience does not require a complex understanding of biomedical engineering, as appears to be argued by the Applicant. Rather, what is understood by an artisan in the field of assembling surgical kits in a clinical setting to be helpful during a surgical aneurysm procedure? Here, for the reasons set forth on record, it is believed that the level of ordinary skill in the art does not require capability for reengineering the physical properties or the design of McCrory's stent; rather, a mere understanding of assembling a surgical kit that contains useful components for performing an aneurysm procedure.

Finally, applicant's references to the declaration filed on January 22, 2001 by Dr. Greff has been noted but are not persuasive, because does not address the issue of whether the ordinary skill in the art being in possession of all references cited would have been motivated to create and surgical kit for ease of access during a surgical process.

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[8] See abstract, table III at page 127; pages 127-129.

New ground of Rejection

Claims 16, 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans US Patent 5,702,361 in view of Chutter.

Evans teaches preparing kits comprising a polymeric embolic composition, a delivery catheter, and a catheter suitable for delivering an endovascular prosthesis.[9] Evans also teaches the use of suitable contrast agents such as iopamidol, polymeric moieties, and solvents encompassed by the instant dependent claims.[10] Evans does not teach the use of stent-grafts.

Chutter teaches the use of stent-grafts for repairing treating post AAA repair.[11]

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the kit taught in Evans by adding a stent-graft or replacing the stent device of Evans with a stent-graft to facilitate ease and convenience during an aneurysm repair procedure. The ordinary would have been motivated to do such modification, because as shown by Chutter employing a stent-graft for treating AAA or an endoleak secondary to AAA surgery would have safe and effective in patients at high risk and use of such device during a AAA repair is foreseeable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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[9] See abstract, col 4, lines 10-49.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

RUSSELL TRAVERS
PRIMARY EXAMINER

[10] See col 7 lines 5-col 8, line 4; col 6, lines 27-35.
[11] See entire abstract, pages 123-125.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).